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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,348	09/13/2004	Gioacchino Coppi	2541-1025	3855

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EXAMINER

NGUYEN, TUAN VAN

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/507,348

Applicant(s)

COPPI, GIOACCHINO

Examiner

Tuan V. Nguyen

Art Unit

3731,

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after the final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 31, 2006 has been entered.
2. Applicants added claim 14. Now claims 1-14 are pending in this present application.

Response to Remarks

3. Applicant's arguments filed on August 31, 2006 with respect to claims 1-10, 12 and 13 have been fully considered but they are moot in view of new ground of rejection.
4. Applicant's arguments filed on August 31, 2006 with respect to claim 11 have been fully considered but they are not persuasive. With respect to "Golden does not show any stiff tubular element". Examiner respectfully traverses applicant's remarks: the tubular element 200 as shown in Figures 1 and 1B of Golden reference is made from stainless steel (see paragraph [0118]).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites limitation "is used in combination" is unclear. It is unclear that applicants want to claim the prosthesis element (10) or applicants want to claim the anastomosis device (2) is adapted for use with a prosthesis element (10). Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. **Claim 11 is rejected under 35 U.S.C. 102(e) as being anticipated by Duhaylongsod et al. (U.S. 6,241,741).**
9. Referring to claim 11, Duhaylongsod discloses (see Figs. 1, 1A, 3, and 3A) an anastomosis device comprising: a tubular connecting element 26 having a first end

34' and a second end (opposite of 34') and first end bears a plurality of barbs 36 or outwardly-projecting slender elements arranged in proximity of at least one of the first end; a tubular prosthesis 12 comprising biocompatible material, wherein the tubular prosthesis is inserted into the tubular connecting element 26 and folded around at 34' so that the outwardly projecting slenders or barbs 36 puncture the tubular prosthesis 12 at everted end 16 (see col. 3, lines 36-60; col. 4, lines 26-46; and col. 6, lines 60-68).

10. **Claims 11 is rejected under 35 U.S.C. 102(e) as being anticipated by Golden et al (U.S. Pub. No. 2004/0050393).**
11. Referring to claim 11, Golden discloses (see Figs. 1A and 1B) an anastomosis device comprises an stainless steel annular element or stainless steel tubular element having a first portion (204) or first end and a second portion (206) or second end and bears a plurality of outwardly-projecting slender elements (210) arranged in proximity of the first end; a tubular prosthesis (G), wherein the prosthesis is inserted into the tubular element and folded around at least an end of the tubular element with outwardly projecting slender elements so that the outwardly projecting slender elements puncture the prosthesis (see paragraphs [0108], [0109], [0118] and [0122]).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
14. **Claims 1-4 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duhaylongsod et al. (U.S. 6,241,741) in view of Nobli (U.S. 3,221,746).**
15. Referring to **claims 1-4 and 14**, Duhaylongsod discloses (see Figs. 1, 1A, 3, and 3A) an anastomosis device comprising: a tubular connecting element 26 having a first end 34' and a second end (opposite of 34') and first end bears a plurality of barbs 36 or outwardly-projecting slender elements arranged in proximity of at least one of the first end; a tubular prosthesis 12 comprising biocompatible material, wherein the tubular prosthesis is inserted into the tubular connecting element 26 and folded around at 34' so that the outwardly projecting slenders or barbs 36 puncture the tubular prosthesis 12 at everted end 16 (see col. 3, lines 36-60; col. 4, lines 26-46; and col. 6, lines 60-68). Duhaylongsod discloses the invention substantially as claimed except for the second end also has barb.

16. Still referring to **claims 1-4 and 14**, Noble discloses (see Figs. 1-3) a device for anastomosis, wherein the device comprises a tubular connecting element having a first end and a second end and both ends bear a plurality of outwardly-projecting barb 12, 13, the free end of barbs facing towards an opposite end from an end at which the barbs are arranged. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use add second end having barbs to tubular element 26, as disclosed by Noble, to incorporate into the device, as disclosed by Duhaylongsod, because this will provide the surgeon the option of securely connecting the second end of the tubular connecting element to a severed blood vessel as quick as the first end as suggested by Noble (see col. 1, line 45 to col. 2, lines 73).
17. Referring to **claim 14**, with respect to the limitation "the prosthetic element is not circumferentially elastic". Here it is noted that synthetic graft for the repair or replacement of vessel having the non elastic characteristic is old and well known in the art.
18. **Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duhaylongsod et al. (U.S. 6,241,741) in view of Noble (U.S. 3,221,746) further in view of Killion et al (U.S. 6,159,238).**
19. Referring to **claims 5 and 9**, the modified device of Duhaylongsod discloses the invention substantially as claimed except for the tubular element has a longitudinal profile section, which is truncoconical, and a transversal section, which decreases in a direction going from the first end to the second end. Killion et al disclose an

expanded stent device (see Figs. 3 and 6) is of a tapered configuration that corresponding to the shape of the ostium regions (see abstract and col. 4, lines 30-40). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the tapered design, as disclosed by Killion et al, to incorporate into the device, as disclosed by Duhaylongsod because the tapered configuration corresponding to the shape of the ostium regions. Furthermore, the tapered configuration is a matter of design choice since such a design as claimed by the applicants does not solved any stated problem.

20. Referring to **claims 6-8**, Grudem et al disclose (see Fig. 3) the slender elements are arranged along the circumference of the proximal to the first portion 20 and second portion (40). The slender elements 22, 26 of the first portion (20) or first end are reciprocally distanced at a smaller step with respect to a step at which the slender elements (42) arranged in proximity of the second portion (40) or second end are reciprocally distanced. The slender elements (22, 26) are longer and more prominent than the slender elements (42). The arrangement of the barb is a matter of design choice since such a design as claimed by the applicants does not solved any stated problem.
21. **Claims 10, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duhaylongsod et al. (U.S. 6,241,741) in view of Noble (U.S. 3,221,746) and further in view of Hughes et al. (U.S. 4,728,328).**

22. Referring to claims 10, 12, and 13, the modified device of Duhaylongsod discloses the invention substantially as claimed except for the suture is used for tight around the tubular element. Hughes discloses (see Figs. 2 and 5) a prosthesis is connected to an anastomosis element by using thread 30. 40 wound around the prosthesis and the anastomosis to secure the prosthesis to the vessel and the suture as shown in Fig. 5 is not in contact with the blood contacting surface of the vessel thereby discouraging thrombosis (see col. 5, lines 50-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the thread wound around the prosthesis, the tubular element and vessel, as disclosed by Hughes, to incorporate into the modified device, as disclosed by Duhaylongsod, because this will improve the security of the connection and avoid thrombosis as suggested by Hughes.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuan V. Nguyen whose telephone number is 571-272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tuan V. Nguyen
October 12, 2006


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
10/14/06